

## AMENDMENTS TO THE CLAIMS

Please amend the claims as follows.

1-23. (canceled)

24. (currently amended) A method for making an aqueous solution of metronidazole greater than 0.75% w/w comprising combining metronidazole, beta-cyclodextrin (BCD), and niacin or niacinamide in an aqueous fluid, wherein the amount of BCD that is combined in the aqueous fluid is sufficient to provide a concentration of BCD in the solution of 0.5% w/w or higher and wherein the aqueous solution is physically stable when stored for one week at 5°C.

25. (previously presented) The method of claim 24 wherein the metronidazole is added to the aqueous fluid after the BCD and the niacin or niacinamide are dissolved in the aqueous fluid.

26. (original) The method of claim 24 which further comprises, after the combination of metronidazole, BCD, and the niacin or niacinamide, adding a gelling agent.

27. (original) The method of claim 24 wherein niacinamide but not niacin is combined.

28. (original) The method of claim 24 wherein niacin but not niacinamide is combined.

29. (original) An aqueous solution that is made by the method of claim 24.

30. (original) An aqueous solution that is made by the method of claim 26.

31. (original) An aqueous solution that is made by the method of claim 27.

32. (original) An aqueous solution that is made by the method of claim 28.

33. (currently amended) A method for the treatment of a dermatologic or mucosal disorder comprising topically applying an effective amount of an aqueous solution of metronidazole having a concentration higher than 0.75% w/w to the site of the disorder and permitting the metronidazole to treat the disorder, wherein the solution comprises beta-cyclodextrin (BCD) at a concentration of 0.5% w/w or higher and niacin or niacinamide, and wherein the solution is physically stable when stored for one week at 5°C.

34. (original) The method of claim 33 wherein the concentration of metronidazole is about 1% or higher.

35. (original) The method of claim 34 wherein the application is once daily.

36. (original) The method of claim 33 wherein the disorder is rosacea.
37. (original) The method of claim 33 wherein the solution comprises niacin and is substantially free of niacinamide.
38. (original) The method of claim 33 wherein the solution comprises niacinamide and is substantially free of niacin.
39. (original) The method of claim 33 wherein the aqueous solution is a gel.
40. (currently amended) A kit for the topical treatment of dermatologic or mucosal disorders comprising a container and an aqueous solution of metronidazole, beta-cyclodextrin, and niacin or niacinamide within said container, wherein the concentration of metronidazole in said solution is higher than 0.75% w/w, the concentration of beta-cyclodextrin is 0.5% w/w or higher, and the concentration of niacin or niacinamide is about 1.0% w/w or higher.
41. (previously presented) The kit of claim 40 wherein the concentration of metronidazole is about 1% w/w or higher.
42. (original) The kit of claim 40 wherein the aqueous solution is a gel.

43. (original) The kit of claim 40 wherein the solution contains niacinamide and is substantially free of niacin.

44. (original) The kit of claim 40 wherein the solution contains niacin and is substantially free of niacinamide.

45. (currently amended) An aqueous solution that is physically stable for at least one week at 5°C comprising metronidazole, a first solubility enhancing agent which is betacyclodextrin, and a second solubility enhancing agent which is niacin or niacinamide, wherein in the solution, the concentration of metronidazole is about 1.0% w/w or higher, the concentration of betacyclodextrin is about 0.5% w/w or higher, and the concentration of niacinamide or niacin is about 0.5% w/w or higher.

46. (previously presented) The aqueous solution of claim 45 wherein the solubility enhancing agent is niacinamide.

47. (previously presented) The aqueous solution of claim 45 wherein the solubility enhancing agent is niacin.

48-52. (canceled)

53. (currently amended) The aqueous solution of claim ~~52~~ 45 which comprises niacinamide and does not comprise niacin.

54. (currently amended) The aqueous solution of claim ~~52~~ 45 wherein the concentration of niacinamide or niacin is about 1.0% w/w or higher.

55. (previously presented) The aqueous solution of claim 54 which comprises niacinamide and does not comprise niacin.

56-58. (canceled)

59. (previously presented) The aqueous solution of claim 45 which is a gel.

60. (canceled)

61. (currently amended) The aqueous solution of claim ~~50~~ 46 which is a gel.

62. (currently amended) The aqueous solution of claim ~~51~~ 47 which is a gel.

63. (currently amended) A method for increasing the solubility of metronidazole in aqueous solution comprising combining metronidazole, betacyclodextrin, and niacinamide or niacin in an aqueous fluid, wherein the concentration of betacyclodextrin in the fluid is about

0.5% w/w or more and the concentration of niacinamide or niacin in the fluid is about 1.0% or higher.

64. (previously presented) The method of claim 63 wherein the aqueous solution is a gel.

65. (previously presented) The method of claim 63 which comprises combining niacinamide in the fluid.

66. (previously presented) The method of claim 63 which comprises combining niacin in the fluid.

67. (previously presented) The method of claim 63 wherein the solubility of metronidazole is increased to 0.75% w/w or more.

68. (previously presented) The method of claim 67 wherein the solubility of metronidazole is increased to about 1.0% w/w or more.

69. (currently amended) The method of claim 63 wherein the betacyclodextrin and the niacin [and] or niacinamide are dissolved in the aqueous fluid before the metronidazole is combined in the fluid.

70. (previously presented) The method of claim 63 wherein a gelling agent is added to the fluid after the metronidazole, betacyclodextrin, and the niacin or niacinamide are combined in the fluid.

71-73. (canceled)

74. (currently amended) A method for increasing the enhancing effect of betacyclodextrin on the solubility of metronidazole in aqueous fluid comprising combining niacin or niacinamide with the betacyclodextrin in the aqueous fluid, wherein the concentration of betacyclodextrin in the fluid is about 0.5% or more and the concentration of niacin or niacinamide is about 1.0% w/w or more.

75. (previously presented) The method of claim 74 wherein the niacin or niacinamide is combined in the fluid with the betacyclodextrin and then metronidazole is added to the fluid.

76. (previously presented) The method of claim 74 wherein niacin is combined with the betacyclodextrin in the aqueous fluid.

77. (previously presented) The method of claim 74 wherein niacinamide is combined with the betacyclodextrin in the aqueous fluid.

78-79. (canceled)

80. (previously presented) The method of claim 24 wherein the betacyclodextrin is crystalline betacyclodextrin.

81. (previously presented) An aqueous solution that is made by the method of claim 80.

82. (currently amended) An aqueous solution comprising metronidazole, betacyclodextrin at a concentration of 0.5% w/w or higher, and niacinamide, wherein the solution is free of crystal or precipitate formation when stored for one week at 5°C.

83. (previously presented) The aqueous solution of claim 82 wherein the concentration of betacyclodextrin is about 1% w/w or higher.

84-87. (canceled)

88. (previously presented) The aqueous solution of claim 82 which is an aqueous gel solution.

89. (currently amended) A method for obtaining an aqueous solution containing metronidazole wherein the aqueous solution contains betacyclodextrin at a concentration greater



than 0.5% w/w, comprising combining in an aqueous fluid metronidazole, betacyclodextrin, and niacinamide wherein the amount of the niacinamide combined in the aqueous fluid is sufficient to provide a dissolved concentration of betacyclodextrin greater than 0.5% w/w at a temperature of 5°C.

90. (previously presented) The method of claim 89 wherein the aqueous solution containing betacyclodextrin at a concentration greater than 0.5% w/w and niacinamide is physically stable for one week at 5°C.

91. (previously presented) The method of claim 89 wherein the aqueous solution is an aqueous gel solution.